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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,836	09/21/2000	Norman G. Anderson	2316-141	1512

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/666,836	ANDERSON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22, 44, 45, 82-84, and 92* is/are pending in the application.

4a) Of the above claim(s) *22, 44, 45, and 82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83, 84, and 92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☒ Other: *duplicate form 1449* .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on October 29, 2001 has been entered as Paper No:11. The claims pending in this application are claims 44, 45, 82-84, and 92 with claims 44, 45, and 82 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Election/Restriction

2. This application contains claims 22, 44, 45, and 82 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

3. Acknowledgment is made of applicant's submission of duplicate form 1449. The original form 1449 was sent to applicant in previous office action in Paper No:10. Upon applicant's request, the examiner agreed to reinitial the duplicate form 1449 and return it to applicant in this office action.

Drawings

4. Applicant's request that " drawing that fully comply with the rules will be submitted after receipt of a notice of allowance" has been granted by the examiner.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 83 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pitcher *et al.,* (Lett. Appl. Microbiol. 8, 151-156, 1989).

Pitcher *et al.,* teach rapid extraction of bacteria genomic DNA with guanidium thiocyanate. In this study, bacteria in broth culture at the end of the exponential growth phase

(~4.8 $\times 10^8$ cells/ml) were pelleted by centrifugation. The pullet was resuspended in 100 µl of buffer, lysed with 0.5 ml of 5 M guanidium thiocyanate, 100 mM EDTA and 0.5% sarkosyl and then extracted with chloroform/2-pentanol in 1.5 ml Eppendorf tube. The purified genomic DNA was digested with different restriction enzymes and run in 0.8% agarose gel in order to observe the digested patterns of genomic DNA (see right column in page 151, left column in page 152, and Figure 2 in page 154). Although Pitcher *et al.*,did not directly show what kind of centrifuge tube was used to pellet bacteria in a broth culture, in the absence of convincing evidence to the contrary, the examiner considered that the centrifuge tube they used in bacteria concentration step was an Eppendorf tube due to small bacteria pellet (rice grain-sized, suggested a small starting volume) after centrifugation of bacteria culture described in this reference (see right column in page 151 and left column in page 152). The limitation in the centrifuge tube could be considered to be inherent to the reference taught by Pitcher *et al.*.

Alternatively, based on small bacteria pellet (rice grain-sized) after centrifugation (suggested a small starting volume), one having ordinary skill in the art at the time the invention was made would be motivated to optimize the experimental conditions (use ~1.5 ml of bacteria) in order to use an Eppendorf tube as a centrifugation tube because it has been routine in the laboratory to use an Eppendorf tube for pelleting a small volume of bacteria. Note that the Eppendorf tube owns all properties of the centrifuge tube described in claim 83 and could be considered as an ultracentrifuge tube (the picture of Eppendorf tube can be found in a lot of company catalogues).

8. Claims 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samadpour *et al.,* (J. Clin. Microbiology, 31, 3179-3183, 1993) in view of Pitcher *et al.,* (1989).

Samadpour *et al.,* teach molecular epidemiology of *Escherichia coli* 0157: H7 strains by bacteriophage lambda restriction fragment length polymorphism analysis. In this study, confluent bacterial cells in agar plates were scraped with several sweeps of a sterile flat-headed toothpick and were suspended in 0.8 ml of Tris buffer before DNA extraction. Genomic DNAs prepared from 168 isolates of *Escherichia coli* O157:H7 were digested with four different restriction enzymes (EcoRI, HindIII, PstI, and PvuII), separated in 0.8% agarose gel (see page 3180, left column), and analyzed for restriction fragment length polymorphisms on Southern blots probed with bacteriophage lambda DNA (see Figures 1 and 2). The isolates analyzed included strains from a recent large multistate outbreak of *E. coli* O157:H7 infection associated with consumption of poorly cooked beef in restaurants, a day-care center cluster, and temporally and geographically unrelated isolates. E. coli O157:H7 isolates recovered from the incriminated meat (considered as known microorganisms) and from 61 of 63 patients (considered as microorganisms from biological samples) from Washington and Nevada possessed identical lambda restriction fragment length patterns. The lambda restriction fragment length polymorphisms observed in 11 of 12 day-care center patients were identical, but they differed from that of the strain associated with the multistate outbreak. E. coli O157:H7 from 42 patients temporally or geographically unrelated to either cluster of infection possessed 39 unique and different lambda restriction fragment length patterns (see abstract in page 3179 and left column in page 3182).

Samadpour *et al.,* do not teach the isolation of bacteria genomic DNA involving a step of pelleting bacteria using centrifugation as described in claims 83.

Pitcher *et al.,* do teach the isolation of bacteria genomic DNA involving a step of pelleting bacteria using centrifugation (see above).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have isolated bacteria genomic DNA from a biological sample and compared the restriction maps between bacteria genomic DNA from a biological sample and known bacteria in view of the reference of Samadpour *et al.,* wherein isolation of bacteria genomic DNA involved a step of pelleting bacteria using centrifugation. One having ordinary skill in the art at the time the invention was made has been motivated to modify the method of Samadpour *et al.,* and combined above methods together because the simple substitution of one DNA isolation method (the method from Samadpour *et al.,* without pelleting bacteria using centrifugation) from another DNA isolation method (the method from Pitcher *et al.,* with pelleting bacteria using centrifugation) during the process of determining the identity of a bacteria in a biological sample would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

9. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pitcher *et al.*, (1989) as applied to claim 83 above, and further in view of Lanoil *et al.,* (Appl. Environ. Microbiol. 63, 1118-1123, March 1997) and Burgoune (US Patent No. 5,756,126, filed on June 7, 1995).

The teaching of Pitcher *et al.,* have been summarized previously, *supra.*

Pitcher *et al.,* do not disclose staining extracted bacteria genomic DNA and immobilizing the DNA on a solid support as recited in claim 92.

Lanoil *et al.,* do teach to label bacteria genomic DNA with fluorescence (see abstract in page 1118 and right column in page 1119).

Burgoune do teach to immobilize genomic DNA from bacteria on a solid support, digest immobilized genomic DNA with a restriction enzyme, and run digested DNA by gel electrophoresis (columns 5, 20 and 21, and Figure 3).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have immobilized fluorescence labeled bacteria genomic DNA on a solid support, digest immobilized genomic DNA with a restriction enzyme, and run digested DNA by gel electrophoresis in view of the references of Lanoil *et al.,* and Burgoune. One having ordinary skill in the art at the time the

invention was made has been motivated to modify the method of Pitcher *et al.,* and combined above methods together because the simple substitution of one DNA digestion method (digestion DNA in a solution) from another DNA digestion method (digestion DNA on a solid support) and the simple substitution of one kind of immobilized genomic DNA (unlabeled DNA) from another kind of immobilized genomic DNA (fluorescence labeled DNA) during the process of determining a restriction enzyme map of a bacteria would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 6 of applicant's remarks, applicant argued that "Pitcher *et al.*,does not teach the claimed elements of an ultracentrifuge tube and ultracentrifugation" since "[A]n ultracentrifuge tube differs from an Eppendorf tube in that it can be spun at a much high rotation rate than an Effendorf tube, and it is made to withstand a much larger G-force than an Eppendorf tube" and

"claim 83 requires that the concentration be performed by ultracentrifuging the ultracentrifuge tube containing the microorganisms".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because the claims do not define what kind of centrifuge tube can be considered as an ultracentrifuge tube and what range of centrifugation speed can be considered as ultracentrifugation. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., much high rotation rate than an Effendorf tube and withstand a much larger G-force than an Eppendorf tube) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
January 3, 2002

ETHAN C. WHISENANT
PRIMARY EXAMINER